

# DiaPex Plus

## Safety Data Sheet

### 1. PRODUCT AND MANUFACTURER INFORMATION

A. Product Name	DiaPex Plus
B. Recommended use of the product and restrictions on its use	
Recommend use of the product	Oinment type root canal filling material
Restrictions on use of the product	Use by specialists
C. Supplier Information (For imported goods, enter the information of the domestic supplier that can be contacted urgently)	
Name of Company	DiaDent Group International
Address	16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea, 28161
Emergency contact number	+82-43-266-2315

### 2. HAZARDS IDENTIFICATION

A. Type of Hazard/Danger      The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.

B. Warning sign items including preventive action statements

Pictorial symbol



Signal words

Warning(GHS07, GHS08)

### 3. COMPOSITION/INFORMATION ON INGREDIENT

Names of ingredients	Synonym	CAS No.	Content (%)
Iodoform	Triiodomethane	75-47-8	35-40
Calcium hydroxide		1305-62-0	20-30
Polydimethylsiloxane		63148-62-9	20-30

### 4. FIRST AID MEASURES

A. When entered into eyes	Seek medical attention. In case of contact with substance, immediately wash skin and eyes with running water for more than 20 minutes.
B. When contacted with skin	Wash the skin with soap and water.
C. When inhaled	Move to a place with fresh air. If you are not feeling well, consult a doctor.
D. When consumed	Rinse your mouth and get medical attention if you are not feeling well.
E. Other medical precautions	Have medical personnel perceive the material and take protective measures.

### 5. FIRE FIGHTING MEASURES

A. a suitable (improper) extinguishing agent	Water fog, Dry powder, foam
B. specific hazards arising from chemicals	Does not occur

### 6. ACIDENTAL RELEASE MEASURES

Use an absorbent material to wipe clean.

### 7. HANDLING AND STORAGE

Safe handling and storage	Use for only professional personnel.
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Use sanitary gloves and tools at the place of treatment.

Do not consume or inhale the product.

Store at 2~27°C/35~80°F

Avoid direct sunlight.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- |                                       |  |
|---------------------------------------|--|
| A. Appropriate engineering management | Use local exhaust or do other engineering management to control the air level below the exposure standard. |
| B. Personal protective equipments     | safety goggles and gloves  |

## 9. PHYSICAL/CHEMICAL PROPERTIES

- |  |           |
|--|-----------|
| A. External                                      |           |
| Composition                                      | Paste     |
| Color  | Yellow    |
| B. Odor  | mild odor |
| C. Odor Threshold                                | No data   |
| D. pH  | No data   |
| E. Melting point / Freezing point                | No data   |
| F. Initial boiling point and boiling point range | No data   |
| G. Flash point                                   | No data   |
| H. Evaporation rate                              | No data   |
| I. Flammability (solid, gas)                     | No data   |
| J. Upper / lower limit of ignition or explosion  | No data   |
| K. Vapor pressure                                | No data   |
| L. Solubility                                    | No data   |
| M. Vaport density                                | No data   |
| N. Specific gravity                              | 1.7~1.8   |
| O. n-octanol / water partition coefficient       | No data   |
| P. Natural ignition temperature                  | No data   |
| Q. Decomposition temperature                     | No data   |
| R. Viscosity                                     | No data   |
| S. Molecular Weight                              | No data   |

## 10. STABILITY AND REACTIVITY

- |   |   |
|---|---|
| A. Chemical Stability and Possibility of Hazardous Reaction | Not applicable  |
| B. Conditions to avoid                                      | Avoid direct light or water exposure. If exposed to light, yellowing may occur. |

## 11. TOXICOLOGICAL INFORMATION

- |                            |  |
|----------------------------|--|
| Cytotoxicity               | No significant clinical signs was observed(MTT)        |
| Maximization Sensitization | No significant clinical signs was observed(Guinea pig) |
| Acute systemic toxicity    | No significant clinical signs was observed(Mouse)      |
| Pyrogen                    | No significant clinical signs was observed(rabbit)     |

## 12. ECOLOGICAL INFORMATION

No ecological problems to be anticipated if properly handled and used.

### 13. DISPOSAL CONSIDERATION

- A. Disposal methods  
Dispose of contents and containers in accordance with the regulations, if specified in the Waste Management Act.  
Discard the container (as specified in the applicable regulations).

### 14. TRANSPORT INFORMATION

- A. UN No.  
DOT, ADR, IMDG, IATA  
Not a regulated substance.
- B. Proper shipment name  
DOT, ADR, IMDG, IATA  
Not a regulated substance.
- C. Risk level in transportation  
DOT, ADR, IMDG, IATA  
Not a regulated substance.
- D. Container level  
DOT, ADR, IMDG, IATA  
Not a regulated substance.
- E. Marine pollutants  
Not applicable.
- F. Special safety measures required or required by the user to know regarding transport or means of transport  
Protect from water, heat or light.

Product is not classified as a dangerous good for transport.

### 15. REGULATORY INFORMATION

The product is a medical device according to the EC-directive 93/42/EEC.  
This product is classified as a medical device under KFPA, FDA.  
This product does not require classification as Dangerous Goods.

### 16. OTHER INFORMATION

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.

- A. Date of initial preparation  
2018-03-19
- B. Number of revisions and date of final revision
- |                        |            |
|------------------------|------------|
| Number of revisions    | 1          |
| Date of final revision | 2020-01-30 |
- C. Others

○ The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate and reliable. It is intended to describe the product according to various safety requirements; however, the manufacturer makes no warranty with respect to the accuracy and completeness of the information or the suitability of the recommendation and assumes no liability to any user thereof.